UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Prevention, Pesticides
and
Toxic Substances

October 4, 1999

Memorandum

Subject: **Phosalone** (PC Code: 097701; DP Barcode: D255208). Decision Memorandum for 09/21/99 Meeting of Metabolism Assessment Review Committee regarding the proposal for parent phosalone as the only residue of concern based on apple and grape metabolism studies.

From: Kristina A. EL-Attar, Chemist
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&
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Through: Whang Phang, Branch Senior Scientist
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&
Richard Loranger, Chair
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Health Effects Division (7509 C)

To: George Kramer, Executive Secretary
Metabolism Assessment Review Committee
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The following document summarizes the deliberations of the Metabolism Assessment Review Committee (MARC) briefing held on 09/21/99 in response to the proposal of parent phosalone as the only residue of concern based on acceptable registrant-submitted apple and grape metabolism studies.

ATTENDANCE

The attendees for the 09/21/99 MARC meeting to consider the proposal of parent phosalone as the only residue of concern based on acceptable registrant-submitted apple and grape metabolism studies were:

George Kramer	Nancy Dodd
Leung Cheng	Kristina EL-Attar
Kit Farwell	John Doherty
Thuy L. Nguyen	Sanjivani Diwan
Christine Olinger	Rick Loranger
William J. Hazel	

DELIBERATION SUMMARY

The MARC raised primarily two issues in relation to the data submitted for committee review in the briefing memorandum (K. EL-Attar, 0913/99). The committee was concerned about: (1) the appropriateness of the registrant's request for a waiver of the animal metabolism studies (specifically the ruminant studies) considering the petitioned uses of phosalone and whether or not the Agency has already granted the waiver, and (2) the appropriateness of considering parent phosalone as the only residue of concern given the potential toxicity of two other plant metabolites also believed to be cholinesterase inhibitors (namely oxophosalone and deschlorophosalone) and the absence of three plant metabolites (6-chlorobenzoxazolone, benzoxazolone, and 2-amino-5-chlorophenol) in the rat toxicity study. Cholinesterase inhibition is the toxicological endpoint of concern for phosalone.

The discussion surrounding the first concern involved Agency consistency in requiring animal metabolism studies regardless of the fact that phosalone is proposed by the registrant for use only on import commodities. Almond hulls and wet apple pomace are the only two possible animal feed items associated with the phosalone submission. Almond hulls are not imported into the U.S. The Agency has previously indicated that a tolerance for residues in/on almond hulls is not required; furthermore, any residues in/on almond hulls are not expected to exceed the tolerance on the raw agricultural commodity. In relation to wet apple pomace, the registrant indicated that the major imported apple commodity is juice (~89%) rather than fresh apples (~9%). Of the countries exporting beef to the U.S., only Canada exports significant quantities (3% of available commodity), and the phosalone market share in Canada is only 6.5%. The registrant indicated that these figures translate into only 0.2% of the available beef supply that would possibly contain phosalone residues if phosalone held the entire market share in Canada. In addition, the Codex Evaluations 1994 contains information in regards to animal metabolism of phosalone. It was concluded that the issue should be deferred to the Chem SAC for further consideration.

The committee's second concern arose from the fact that two of the plant metabolites

(oxophosalone and deschlorophosalone) are comparably or potentially more toxic than the parent compound and that three of plant metabolites (6-chlorobenzoxazolone, benzoxazolone, and 2-amino-5-chlorophenol) were not identified in the rat toxicity study. The committee concluded that the latter three metabolites are not likely to be cholinesterase inhibitors. It was also decided that deschlorophosalone is not of concern based on its low percent of the total radioactive residue (TRR). It was suggested that the toxicity of oxophosalone–arguably the active form of the parent compound responsible for cholinesterase (ChE) inhibition–is accounted for through the conversion of parent phosalone in the animal and that consideration of parent phosalone as the only residue of concern is legitimate since the values for the acute and chronic reference doses (RfD) should be reflective of the metabolite in question. The committee recommended not to include oxophosalone, the oxon, in the tolerance expression or the risk assessment based on its low percent TRR. This decision may be reevaluated if borderline dietary risks were found for the parent compound.

RESPONSE TO QUESTIONS ADDRESSED TO COMMITTEE

The section below contains the original question reprinted from the briefing memorandum to the committee and the committee's associated response to those questions.

Q. The residue chemistry suggests parent phosalone as the only residue of concern. Does the committee, upon reviewing the material in this document, agree that parent phosalone is the only residue of concern?

A. The committee decided that parent phosalone is the residue of concern.

Q. Should the U.S. harmonize with Codex MRLs, which are lower than the current tolerances but higher than the proposed reassessed tolerance for the imported commodities of interest?

A. This issue should be deferred to the Chem SAC.

cc: **Deanna P. Scher**, Review Manager, Special Review and Reregistration Division, Office of Pesticide Programs;
William J. Hazel, Risk Assessor, Health Effects Division, Office of Pesticide Programs;
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